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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,131

11/07/2005

John P. Maye

61843USN(51035)

2561

21874

7590

02/18/2009

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EXAMINER

FLOOD, MICHELE C

ART UNIT

PAPER NUMBER

1655

MAIL DATE

DELIVERY MODE

02/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,131	Applicant(s) MAYE, JOHN P.	
	Examiner Michele Flood	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 1, 2008 has been entered. Further acknowledgment is made of Applicant's cancellation of Claims 6, 13 and 14.

Claims 1-5, 11 and 12 are under examination.

Response to Arguments

Claim Objections

Claim 1 is objected to because of the following informality: There is an apparent misspelling in Claim 1. Applicant may overcome the objection by replacing “*fibriosolvens*” with *fibrisolvens*. Appropriate correction is required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the hop acid is" in line 1. There is a lack of clear antecedent basis for this limitation in the claim. Applicant may overcome the rejection by replacing the limitation with the hop acids are.

Claim 12 recites the limitation "the digestive system" in line 1. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by replacing "system" with systems.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 11 and 12, as amended, remain rejected under 35 U.S.C. 102(b) as being anticipated by Papadopoulos et al. (U). Applicant's arguments have been fully considered. However, the rejection remains for the reason set forth in the previous Office action but slightly altered and for the reason set forth herein.

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Applicant claims a method of preparing an organic food supplement useful to inhibit *Ruminococcus albus*, *R. flavefacienes*, *Butyrivibrio fibrisolvens*, or *Methanobacterium ruminatium* using *Humulus lupulus* (hop) acids for livestock comprising mixing the hop acids for oral ingestion with a livestock feed wherein the hop acids are mixed with the feed in an amount to inhibit undesirable bacteria selected from the group consisting of *Ruminococcus albus*, *R. flavefacienes*, *Butyrivibrio fibrisolvens*, and *Methanobacterium ruminatium*, commonly found in digestive systems of livestock. Applicant further claims the method of claim 1 wherein the hop acids as well as their corresponding salts are selected fore at least one of the group consisting of alpha acids, beta acids, isoalpha acids, rho-isoalpha acids, tetrahydroisoalpha acids and hexahydroisoalpha acids. Applicant further claims the method of claim 2 wherein the beta acids are selected from at least one of the group consisting of lupulone, colupulone, and adlupulone. Applicant further claims the method of claim 1 wherein the hop acid is mixed with the feed results in an amount of 2 parts per million (ppm) of hop acid present in fluid of the digestive system of livestock. Applicant further claims the method of claim 1 wherein the livestock is selected from the group consisting of cattle, poultry, horses, pigs, and zoo animals. Applicant further claims the method of claim 1 wherein an amount of hop acid mixed with the feed is capable of increasing a level of propionate in the digestive system.

Papadopoulou teaches mixing barley (read herein as a livestock feed) with *Humulus lupulus* hop beta-acid to prepare a composition (read herein as an organic food supplement for oral ingestion), wherein the hop-beta acid used was at the levels of

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1 ppm and 10 ppm of barley. See page 184, Column 2, first line of second paragraph. Papadopoulou further teaches a composition comprising 10 ppm of hop beta acid and barley composition that was effective in eliminating the growth of *Escherichia coli*, yeast and fungi, which are undesirable bacteria commonly found in digestive systems of livestock. On page 184, Column 1, second paragraph in its entirety, bridging Column 2, Papadopoulou teaches, "It is well recognized that hop compounds possess antimicrobial properties and these are now being used as preservatives [citations omitted]. The addition of 1 ppm of α -acid during steeping, or at cast, eliminated *Chromobacterium*, *Clavibacterium* and fungi."

Applicant argues that the teachings of Papadopoulou pertain to the inhibition of certain bacteria typically found in the malting and/or brewing process; and, unlike the instantly claimed invention, does not teach a method to make a food supplement used to control bacteria found in livestock, including the claim-designated microorganisms. Applicant's arguments have been fully considered but found unpersuasive because the instantly claimed invention is a one step method comprising mixing hop acids with a feed in an amount to inhibit the claim-designated undesirable bacteria *Ruminococcus albus*, *R. flavefacienes*, *Butyrivibrio fibrisolvens* or *Methanobacterium ruminatium*. As set forth above, Papadopoulou teaches mixing the same ingredients and the same amounts of the ingredients disclosed by Applicant for preparing an organic food supplement useful to inhibit *Ruminococcus albus*, *R. flavefacienes*, *Butyrivibrio fibrisolvens*, or *Methanobacterium ruminatium*. Thus, the claim functional effect for the inhibition of the claim-designated microorganisms is considered inherent to the method

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of preparing the composition taught by the cited reference. Moreover, given that Papadopoulou teaches mixing barley with hop beta acids (which inherently would include at least lupulone since lupulone is also referred in the art as beta hop acids) in an amount of 10 ppm, the claim-designated functional effect of "2 parts per million (ppm) of hop acid present in fluid of the digestive system fluid of livestock", and the claim-designated functional effect of "wherein an amount of hop acid mixed with the feed is capable of increasing a level of propionate in the digestive system" are deemed inherent to the method of making of the organic food supplement taught by Papadopoulou. Given that Papadopoulou teaches mixing barley with hop beta acids (which inherently would include at least lupulone since lupulone is also referred in the art as beta hop acids) in an amount of 10 ppm, the claim-designated limitation of an animal feed "wherein the effective amount of hop acid mixed with the feed results in from about 1 parts per million (ppm) to about 30 ppm of hop acid in fluid of the digestive system of the livestock" is deemed inherent to the method of making the composition taught by Papadopoulou.

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

The reference anticipates the claimed subject matter.

Claims 1, 2, 5, 11 and 12, as amended, remain rejected under 35 U.S.C. 102(b) as being anticipated by Arnould et al. (V or W; Translation of foreign non-patent literature provided herein.). Applicant's arguments have been fully considered. However, the rejection remains for the reason set forth in the previous Office action but slightly altered and for the reason set forth herein.

Applicant's claimed invention was set forth above.

Arnould teaches a method of making an organic food supplement for livestock comprising mixing an effective amount of isohumulone and feed plant, such as Lucerne (also known in the art as alfalfa) and barley. Arnould teaches mixing feed plant, such as alfalfa and barley, with hop acids comprising including hop alpha acids, wherein the amount of the alpha acids was 61 mg of isohumulones per kg of fresh feed plant. See page 11, under "*3.1 Chemical composition of the malt and hop dregs*", wherein the amount of hop acid mixed with the feed results from about 1 parts per million to about 30 ppm of hop acid.

Applicant readily admits, "Arnould is directed to formation of a food supplement comprising both hop aid and malt dregs for an animal feed". Nevertheless, Applicant argues that the process of making the food supplement taught by Arnould was to determine the effects of hop acids/malt dregs on milk production. Thereby, Applicant argues that Arnould does not teach a method of making a food supplement used to control bacteria found in livestock, including the claim-designated microorganisms.

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Applicant's arguments have been fully considered but found unpersuasive because the instantly claimed invention is a one step method comprising mixing hop acids with a feed in an amount to inhibit the claim-designated undesirable bacteria *Ruminococcus albus*, *R. flavefacienes*, *Butyrivibrio fibrisolvens*, or *Methanobacterium ruminatium*. As set forth above, Arnould teaches mixing the same ingredients and the same amounts of the ingredients disclosed by Applicant for preparing an organic food supplement useful to inhibit *Ruminococcus albus*, *R. flavefacienes*, *Butyrivibrio fibrisolvens*, or *Methanobacterium ruminatium*. Thus, the claim functional effect for the inhibition of the claim-designated microorganisms is considered inherent to the method of preparing the composition taught by the cited reference. Moreover, given that Arnould teaches mixing either alfalfa or barley with hop alpha acids (such as isohumulones) in an amount of 61 mg per 1 kg of fresh feed plant the claim-designated functional effect of "2 parts per million (ppm) of hop acid present in fluid of the digestive system fluid of livestock", and the claim-designated functional effect of "wherein an amount of hop acid mixed with the feed is capable of increasing a level of propionate in the digestive system" are deemed inherent to the method of making of the organic food supplement taught by Arnould. Given that Arnould teaches mixing either alfalfa or barley with hop alpha acids (such as isohumulones) in an amount of 61 mg per 1 kg of fresh feed plant, the claim-designated limitation of an animal feed for cattle "wherein the effective amount of hop acid mixed with the feed results in from about 1 parts per million (ppm) to about 30 ppm of hop acid in fluid of the digestive system of the livestock" is deemed inherent to the composition taught by Arnould.

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It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Moreover, there are no ingredients contained in the composition taught by Arnould to preclude the use of the reference composition as an organic food supplement for livestock.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1- 5, 11 and 12, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (BE: GB 2330076A) in view of Makin (BC; GB 120,166) and Goldreich (N).

Applicant's claimed invention of Claims 1, 2, 5, 11 and 12 was set forth above. Applicant further claims the method of Claim 2, wherein the hop acids are selected from at least one of the group consisting of humulone, colupulone, and adlupulone.

Johnson teaches a method of preparing an organic food supplement comprising mixing an extract of *Humulus lupulus* containing alpha-acids (lupulones), beta-acids (lupulones) and desoxy alpha acids with a food product or a solid food wherein the hop acids are mixed with the food in an amount to inhibit undesirable bacteria found in digestive systems of livestock. Johnson teaches that the hop extracts are added to a food product or other vehicle in solution to achieve at least about one part per million by weight of hop extract in the GI tract or stomach, preferably 5 ppm-100 ppm of beta acids. The compositions prepared by the method taught by Johnson comprise at least 1 ppm of hop extracts or more preferably, 5, 10 and 100 ppm.

The teachings of Johnson are set forth above. While Johnson teaches mixing hop extracts with a food product in the making of food supplement for inhibiting undesirable bacteria found in the digestive system of livestock, Johnson does not specifically teach mixing the hop acids with an animal feed.

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Makin teaches a process for the production of foodstuffs for oral ingestion by cattle, animals or birds, as well as human beings, comprising adding 15% of spent hops or derivatives to vegetable substances such as cereals. On page 1, lines 30-32, Makin teaches, "An animal food for use by itself or combined with other food substances has been composed of yeast, hops and commercial peat moss combined if desired with molasses in any suitable manner to form a meal." In another instance, Goldreich teaches a fodder comprising bean stalk to which have been added 5% to 15% of dried spent hops and the total mixture has been milled and made into pellets. Goldreich teaches that the slightly bitter taste of hops makes the feed palatable to the animal and materially aids digestion. Although Makin and Goldreich are silent to the presence of alpha-acids and beta-acids in the livestock feed, it is known in the art that alpha-hop acids and beta-hop acids are found in the lupulin glands of the hop cones (both of which are contained in the hops products disclosed by the cited references). Accordingly, the hops products within the animal feed taught by Makin and Goldreich would intrinsically contain such acids therein. Thus, at the time the invention was made, it was known in the art that livestock feed is useful in the making of foodstuffs comprising alpha-hop acids and beta-hop acids. Therefore, an artisan of ordinary skill would have had a reasonable expectation that using the animal feed/fodder/livestock feed containing alpha-hop acids and beta-hop acids taught by either Makin or Goldreich would be successful. This reasonable expectation of success would have motivated the artisan to mix the feed/fodder/livestock feed of either Makin or Goldreich with the *Humulus lupulus* extract containing humulones, lupulones and desoxy alpha acids of Johnson to

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provide the claimed method of preparing an organic food supplement useful for oral ingestion by livestock, especially given the beneficial teachings of using spent hops or hops or hop meal or hop derivatives in animal feed, its aid in digestion and its palatability as discussed above.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
February 13, 2009

/Michele Flood/
Primary Examiner, Art Unit 1655